

Product Data Sheet

Product name: Chondroitin Sulphate Porcine CPC 90% HPLC 70%

AC Code: AC05034a

1. Technical Data Sheet

CAS number	9007-28-7	
Compliance (Food/ Pharmacopoeia /FCC/Feed)	Food & Feed	
Source (animal, plant, mineral, petrochemical)	Animal	
Item	Standard	Analysis Method
Sensory		
Appearance	White or almost white, hygroscopic powder	Visual
Typical Analysis		
Chondroitin Content	Min 90% by CPC (Dry basis)	USP
Chondroitin Content	Min 70% by HPLC (Dry basis)	Enterprise Standard
Particle Size	100% pass through sieve 80 mesh	US Standard Sieve
Water Solubility	Freely soluble in water, practically insoluble in acetone and in ethanol (96 per cent)	Enterprise Standard
Loss on drying	≤ 12.0%	USP <731> Ph.Eur.2.2.32
PH	5.5 ~ 7.5	USP <791>
Chloride	0.5% Max	USP <221>
Sulfate	0.24% Max	USP <221>
Protein	≤ 6.0%	USP
Residue on ignition	20% ~ 30%	USP <281>
Specific Rotation	-20°~ -30°	USP <781S>
Heavy Metals		
Heavy metals	≤ 10 ppm max	USP <231> II Ph.Eur.2.4.8
Lead	≤ 3.0 ppm	USP <251> Ph.Eur.2.4.10
Arsenic	≤ 1.0 ppm	USP <211> II Ph.Eur.2.4.2
Cadmium	≤ 1.0 ppm	USP <233>
Mercury	≤ 0.1 ppm	USP <233>
Microorganism		
Total Plate Count	≤ 1,000 CFU/g	USP <2021> Ph.Eur.2.6.12
Yeast and Mold	≤ 100 CFU/g	USP <2021> Ph.Eur.2.6.12
E. Coli	Negative/g	USP <2021> Ph.Eur.2.6.13
Salmonella	Negative/10g	USP <2021>

		Ph.Eur.2.6.13
Package	25kgs/drum	
Shelf life	2 Year When Properly Stored	
Storage	The product may be stored for 24 months from the date of manufacture in the unopened original container and at room temperature. It should be protected from light, heat, oxygen and moisture. Keep the container tightly closed. Once opened, use contents quickly	
Intended Application	Suitable for manufacturing tablets and hard-shell capsules. Also as a food nutrition enhancer for food and beverage	

2.Origin & ingredient

Country of origin of the product: China

Origin Statement: available ☒

This Product Is A Pure Material ☒		This Product is a Compound Material ☐	
Composition of the products		100% Chondroitin Sulphate	
Animal Origin	☐ Bovine		Specific Source
	☒ Porcine		Specific Source
	☐ Avian,		Specific Source
	☐ Others:		Specific Source:
Mineral Origin	☐		Specific Source:
Synthetic	☐	Starting Material:	Origin:
		Starting Material:	Origin:
Biotechnological Processing	☐ Catalysis By Enzymes		Name Of Enzyme: Sources Of Enzymes:
	☐ Micro -Organisms		Source Of Medium:
Botanical Origin	Botanical Name:		/
	Part:		/
	Wild Or Cultivated:		/
	Country Of Origin:		China
	Solvent Used:		Ethanol

3.Nutrition data

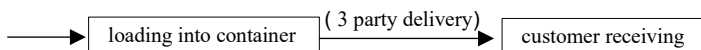
Nutritional composition	☒ per 100g	☐ per serving
☐ Energy(kJ) ☒ Energy(kcal)	269.2 kcal	
Fat (g)	<0.1	
Carbohydrates (g)	42.1	
Protein (g)	25.2	
Remarks: Nutrition data are obtained by 3 rd party lab; tested on a yearly basis		

4.Manufacture details

Manufacturer name:	Yantai Ruikangda Biochemical Products Co., Ltd
Address:	Tianmu Road Development Zone,Laiyang,Shandong,P.R.China

Main products:	Chondroitin Sulphate		
Capacity of production	1,000mt		
Number Of Employees In Production: 50		Number Of Employees In QA/QC.: 6	
Quality And Food Safety Management System Certificated By Accredited Authority. E.G.: ISO Series, GFSI Series HACCP GMP、Cgmp FAMI-QS、GMP+	ISO9001 Series: ☐ ISO9001 ☒ ISO22000 ☐ ISO14001 ☐ ISO45000 GFSI Series: ☐ BRC ☐ FSSC22000 ☐ IFS ☐ SQF ☒ GMP ☒ HACCP ☐ FAMI-QS ☐ GMP+		
Product Related Certificates	☒ HALAL	☒ KOSHER	☐ IP ☐ ORGANIC
Suitable For Vegan	☒ YES	☐ NO	

5.Process Quality And Food Safety							
Flow Chart: This Product Specification Has Listed The Detailed Process Flow Chart Of Each Step Of The Actual Production Process From Raw Material Pretreatment To Finished Product Warehousing, Including Possible Additives, Processing Aids, Steps To Remove Foreign Matters, CCP, Water Used, Compressed Air Etc.		Integrity Flow Chart Available ☒					
Foreign Body Control							
Have Implemented Control Procedures For Glass, Fragile Plastic Materials ☒							
☒ Sieve	Location: Before Packing	Mesh Size: 0.2mm					
☒ Magnetic Device	Location: Before Packing	Magnetic Strength: 13400Gauss					
☐ Filter Bag Or Filter Membrane	Location:	Aperture Of Filtering Device:					
Pest Control							
Conducted By Manufacturer ☐ By External Contractor ☒ Name Of Contractor: Inspection Frequency: 1 Time Per Year							
Batch No.& Traceability							
Batch Size:	1,000kgs						
Batch Definition:	Signification Of The Batch No. By An Example: Abbr. Of Customer + Year + Month + Date Sequence Produced By This Day ACER20201205: Acer + year + month + date						
We Confirm That We Perform Batch And Traceability Management On The Whole Process From Raw Material Receiving, Production Process, Storage And Transportation, By Focusing On Raw Materials, Semi-Finished Products, Production Processing And Transportation, Related Records And Product Labels. Take Traceability Exercise On A Annual Basis.							
Supply Chain Custody							
List All The Stages In The Process Of Supply Chain Including Detail Of Every Link Back To Farm, Field Or Ocean. Every Time The Raw Material Is Moved, Paid For, Handled, Stored Or Processed, And Final To Customer							
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">product loading at plant</td> <td style="padding: 5px;">(domestic transportation)</td> <td style="padding: 5px;">loading into container at port warehouse</td> <td style="padding: 5px;">(sea transportation)</td> <td style="padding: 5px;">warehousing & storage overseas</td> </tr> </table>			product loading at plant	(domestic transportation)	loading into container at port warehouse	(sea transportation)	warehousing & storage overseas
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GMO Declaration	YES	NO
The Product Contain Or Consist Of GMO	☐	☒
The Product Is Produced From GMO Or Contain Ingredients Produced From GMO (Irrespective Of Whether There Is NDA Or Protein Of GM Origin In The Final Production)	☐	☒
This Product Is Produced By Means Of GM Microorganism Including Precursor Substances, E.G. With Gmos Or Genetically Modified Microorganisms Processing Aids(Bacteria, Yeast,..)	☐	☒
This Product Is Produced With The Help Of Enzymes, Which Were Obtained From GMOs	☐	☒
Does The Product Contain Any Ingredients From Animal? If Yes, Are Genetically Modified Crops Contained In The Feed For The Animal?	☒ ☐	☐ ☒
We Confirm That This Product Complies With Regulations EC/1829/2003 And EC1830/2003 And Keep NON-GMO Statement Available		☒

6. Allergen declaration

We have carefully reviewed this product according to EU Regulation 1169/2011 and modifications and confirm the following:

	Direct incorporation as a base raw material or in a derivative form (don't forget the carriers, the additives and the processing aids)		CROSS CONTAMINATION					
			Presence on the production line		Presence on the production workshop		Presence on the production factory	
	Yes (precise nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No
Cereals containing gluten(1) and products thereof		N		N		N		N
Crustaceans and products thereof		N		N		N		N
Eggs and products thereof		N		N		N		N
Fish and products thereof (2)		N		N		N		N
Peanuts and products thereof		N		N		N		N
Soybeans and products thereof (3)		N		N		N		N
Milk and products thereof (including lactose)(4)		N		N		N		N
Nuts (5) or products thereof		N		N		N		N
Celery and products thereof		N		N		N		N
Mustard and products thereof		N		N		N		N
Sesame seeds and product thereof		N		N		N		N
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO2		N		N		N		N
Lupines and products thereof		N		N		N		N

Mollusc and product thereof		N		N		N		N
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- (1) Cereals which contain gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) except: wheat-based glucose syrups including dextrose, wheat-based maltodextrins, glucose syrups based on barley, cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;
- (2) Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine;
- (3) Except fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources;
- (4) Except when used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages, lactitol;
- (5) almond (*Amygdalus communis* L.) hazelnuts (*Corylus avellana*), walnut (*Juglans regia*), cashew (*Anacardium occidentale*), pecan nuts (*Carya illinoensis*), brazil nut (*Bertholletia excelsa*), pistachio nut (*Pistacia vera*), macadamia nut and queensland nut (*Macadamia terniflora*) and products thereof, except nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

7. Non Irradiation

(According To Eu Directive 1999/2/EC & 1999/3/EC)

This Product Has Been Treated With Ionising Radiation	☐ Yes	☒ No
None Of The Raw Materials We Used For This Product Have Been Treated With Ionising Radiation.	☐ Yes	☒ No
We Confirm Above Non-Irradiation Statement Is Available	☒	

8. Nanomaterial

(According To Eu Regulation (Eu) No. 1169/2011)

This Product Does Contain Any Nanomaterials As Defined In Eu Food Legislation	☐ Yes	☒ No
This Product Has Been Made With Nanotechnology	☐ Yes	☒ No
We Confirm Above Non-Nanomaterial Statement Is Available	☒	

9. Residual Solvents

(According To UE Directive 2009/32 Modified By (UE) 2010/59; EP5.4; USP476; ICH Q3C(R7))

For This Product Following Solvents Are Used During Production Process:	☒ Solvent Used ☐ Solvent Not Used	
Solvent A: Max Residual Level:		
Solvent B: Max Residual Level:		
We Confirm Solvent Residual Of This Product Complies With:	☒ EP8.0 ☒ USP <476> ☒ ICH Q3C(R7) ☒ Directive 2010/59/EU	
We Confirm Solvent Residual Statement Is Available	☒	

10. Pesticide Residual

(According To EC 396/2005; EP07; USP <561>)

This Product Is Of Vegetable Origin	☐ YES ☒ NO
We Confirm Pesticide Residual Of This Product Complies With:	☒ EC 396/2005 ☒ EP 07/2008 ☒ USP<561> ☒ N/A
Pesticide Residual Statement Available	☒

11.BSE/TSE Information

(According To EU Legislation 999/2001; EP General Chapter 5.2.8)

Cattle, Sheep, Goats And Animals That Are Naturally Susceptible To Infect With Transmissible Spongiform Encephalopathy Agents Or Susceptible To Infection Through The Oral Route Other Than Humans And Non-Human Primates Are Defined As “ESE-Relevant Animal Species
Pigs Ad Birds Are Not Naturally Susceptible To Infection Via The Oral Route; Therefore, They Are Not TSE-Relevant Animal Species. Dogs, Rabbits And Fish Are Not TES-Relevant Animal Species.”

The Product Contains Ingredients Of Ruminant Origin And No Materials Derived From, Or Exposed To Ruminants Affected By Or Under Quarantine For Transmitting Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE)	☐ YES ☒ NO ☐ NA
In The Manufacturing Of This Product, There Is Raw Or Source Material And /Or Reagent Used That Is Of Animal Origin I.E. Bovine, Serum-Albumin, Enzymes, Culture Broths Including Those Used To Prepare Working Or Master Cell Tanks	☐ YES ☒ NO
Equipment/Systems/Tools Use For Processing Or Storage Of The Material Comes Into Contact At Any Time With Materials Of Animal Origin (E.G., Components Of Media Filler Used To Check Such System)	☐ YES ☒ NO
The Material Is Purified By Using Solvents, Chromatographic Media Or Buffers That Contain Components Of Animal Origin	☐ YES ☒ NO
We Confirm This Product Complies With:	☒ EU Legislation 999/2001& ☒ EP General Chapter 5.2.8
We Confirm BSE/TSE Statement Is Available	☒ YES

12.Contaminants Information

(According To EU Regulation NO.1881/2006 And NO.629/2008 As Regards Maximum Levels For Certain Contaminants In Foodstuff)

●Aflatoxin B1 <5ppb ●Aflatoxins B1 + B2 + G1 + G2 <10ppb ●Ochratoxin A <15ppb ●Melamine	☒ YES ☐ NO ☐ NA	(Frequency For Surveillance Test Or Batch Test)
For Polycyclic Aromatic Hydrocarbons, In Cocoa Fibre, Banana Chips, Food Supplements And Their Preparations, Dried Herbs And Dried Spices: ●Maximum Level Of 10 µG/Kg Of Benzo(A)Pyrene	☒ YES ☐ NO ☐ NA	(Frequency For Surveillance Test Or Batch Test)



●50 µG/Kg For The Sum Of PAH4 (PAH4; Benzo[A]Pyrene,Chrysene, Benz[A]Anthracene And Benzo[B]Fluoranthene) In Food Supplements		
We Confirm This Product Complies With NO.1881/2006 And NO.629/2008 And Keep Compliance Statement Available	☒ YES	